Serial No.: 09/423,715

Filed: January 12, 2000

Page: 2

In the Claims

Please amend the claims by replacing all prior versions of the claims pursuant to 37 C.F.R. §1.121 as modified by 68 Fed. Reg. 38611 (June 30, 2003) as follows:

 (Currently Amended) A topical composition for mutual enhancement of transdermal permeation of at least a first and a second pharmaceutically acceptable components which are both pharmacologically active agents, the composition comprising

an emulsion of at least one discontinuous phase in a continuous phase, the or each at least one discontinuous phase comprising a eutectic mixture of at least first and second pharmacologically active agents and the continuous phase comprising a pharmaceutically acceptable carrier, the eutectic mixture having a melting point below 40°C ; and

at least one compatible emulsifying agent,

when the first pharmacologically active agent is a local anesthetic, the second pharmacologically active agent is not a local anaesthetic, wherein when the pharmacologically active agent is local anesthetic, the first pharmacologically active agent is not a local anesthetic, and wherein the first and the second pharmacologically active agents are each prophylactic or a therapeutic agent, and

wherein one of the first the second or pharmacologically active agent is chlorocresol, chlorbutanol, methyl nicotinate, triprolidine, promethazine, trimeprazine, sulfiram, oxybutynin, testosterone enanthate or choline salicylate.

Serial No. : 09/423,715

Filed : January 12, 2000

Page: 3

2. (Previously presented) The topical composition according to Claim 1, in which the first pharmacologically active agent has a melting point between 35 and 75°C, and the second pharmacologically active agent has a melting point between -40°C and 150°C.

- 3. (Previously presented) The topical composition according to Claim 1, in which the topical composition additionally includes, in the eutectic mixture, a third pharmaceutically acceptable component.
- 4. (Previously presented) The topical composition according to Claim 3, in which the third pharmaceutically acceptable component has a melting point between 40 and 150° C.
- 5. (Previously presented) The topical composition according to Claim 3 or 4, in which the third component is a third pharmacologically active agent.
- 6. (Previously presented) The topical composition according to Claim 3, in which the topical composition additionally includes, in the eutectic mixture, a fourth pharmaceutically acceptable component.
- 7. (Previously presented) The topical composition according to Claim 6, in which the fourth pharmaceutically acceptable component has a melting point between 40 and 150°C.
- 8. (Previously presented) The topical composition according

Serial No.: 09/423,715

Filed: January 12, 2000

Page: 4

to Claim 6 or 7, in which the fourth component comprises a fourth pharmacologically active agent.

- 9. (Previously presented) The topical composition according to Claim 1, in which said at least one discontinuous phase consists essentially of the eutectic mixture.
- 10. (Canceled).
- 11. (Previously presented) The topical composition according to Claim 1, in which the second pharmacologically active agent is selected from the group consisting of non-steroid anti-inflammatory arylpropionic agents, narcotic analgesics, anti-fungal agents, antibacterial agents, anticholinergics, anthelmintics, antihistaminics, and antihypertensives.
- 12. (Previously presented) The topical composition according to Claim 8, in which the third and fourth pharmacologically active agents are each selected from the group consisting of non-steroid anti-inflammatory agents, narcotic analgesics, anti-fungal agents, antibacterial agents, anticholinergics, antihypertensives, antihistaminics, and anthelmintics.
- 13. (Previously presented) The topical composition according to Claim 3 or 4, in which the third pharmaceutically acceptable component is lauric acid, stearyl alcohol, menthol, thymol, cinnamic acid, or an ester thereof.
- 14. (Currently Amended) The topical composition according to

Serial No.: 09/423,715

Filed: January 12, 2000

Page: 5

Claim 1, in which the pharmaceutically acceptable carrier is substantially hydrophilic, said carrier comprising substantially water as the continuous phase.

- 15. (Previously presented) The topical composition according to Claim 1, in which the pharmaceutically acceptable carrier contains at least one gelling or suspension agent.
- 16. (Currently Amended) The topical composition according to Claim 15, in which the gelling or suspension agent is selected from the group consisting of carbomers, modified celluloses, naturally-occurring synthetic or semisynthetic gums, modified starches, co-polymers formed between maleic anhydride and methyl vinyl ether, colloidal silica and methacrylates or , and a mixture thereof.
- 17. (Currently Amended) The topical composition according to Claim 1, in which the topical composition is in the form of a gel, lotion, suspension, cream, aerosol spray, is deposited on a transdermal patch, or medicated dressing or is incorporated within soft gelatin capsule.
- 18. (Previously presented) The topical composition according to Claim 1, in which the emulsifying agent is selected from the group consisting of non-ionic, cationic and anionic surfactants.
- 19. (Previously presented) The topical composition according to Claim 18, in which the emulsifying agent is a non-

Serial No.: 09/423,715

Filed: January 12, 2000

Page: 6

ionic surfactant.

20. (Previously presented) The topical composition according to Claim 1, in which the at least two pharmacologically active agents are structurally and/or pharmacologically diverse.

21 - 22. (Canceled)

23. (Currently Amended) A method for mutual enhancement of dermal permeation from an accessible body surface of a human of at least a first and a second pharmaceutically acceptable components which are both pharmacologically active agents, the method comprising

applying a topical composition to a human in need thereof for mutual enhancement of transdermal permeation of at least the first and second pharmacologically active agents, the composition comprising

an emulsion of at least one discontinuous phase in a continuous phase, the or each at least one discontinuous phase comprising a eutectic mixture of at least first and second pharmacologically active agents and the continuous phase comprising a pharmaceutically acceptable carrier, the eutectic mixture having a melting point below 40°C; and at least one compatible emulsifying agent,

wherein when the first pharmacologically active agent is a local anesthetic, the second pharmacologically agent is not a local anesthetic, wherein when the second pharmacologically active agent is a local anesthetic, the first

Serial No.: 09/423,715

Filed: January 12, 2000

Page: 7

pharmacologically active agent is not local anesthetic, and wherein the first and the second pharmacologically active agents are each prophylactic or a therapeutic agent, and wherein one of the first or the second pharmacologically active agent is triclosan, chlorocresol, chlorbutanol, nicotinate, triprolidine, methyl promethazine, trimeprazine, sulfiram, oxybutynin, capsaicin, testosterone enanthate or choline salicylate, wherein the topical application to a human in need thereof is to an accessible a body surface of an animal the human.

- 24. (Canceled).
- 25. (Previously presented) The topical composition according to claim 2, wherein the first pharmacologically active agent has a melting point between 40 and 50°C, and the second pharmacologically active agent has a melting point between -5 and 90°C.
- 26. (Previously presented) The topical composition according to claim 4, wherein the third pharmaceutically acceptable component has a melting point between 40 and 75°C.
- 27. (Previously presented) The topical composition according to claim 7, wherein the fourth pharmaceutically acceptable component has a melting point between 40 and 75°C.
- 28. (Previously presented) The topical composition according

Serial No.: 09/423,715

Filed : January 12, 2000

Page: 8

to claim 11, wherein the second pharmacologically active agent is selected from the group consisting of triclosan, chlorocresol, capsaicin, trimeprazine, choline salicylate, methyl nicotinate, ibuprofen, ketoprofen, fenoprofen, flurbiprofen, etodolac, fentanyl, econazole, ketoconazole, mupirocin, chlorbutanol, clindamycin, iodine, oxybutynin, tetramisole, triprolidine, promethazine, and propranolol.

- 29. (Previously presented) The topical composition according 12. Claim wherein the third and fourth pharmacologically active agents are each selected from consisting of triclosan, the chlorocresol, capsaicin, trimeprazine, choline salicylate, methyl nicotinate, ibuprofen, ketoprofen, fenoprofen, fentanyl, flurbiprofen, etodolac, econazole, chlorbutanol, ketoconazole, mupirocin, clindamycin, iodine, oxybutynin, propranolol, triprolidine, promethazine, and tetramisole.
- 30. (Previously presented) The topical composition according to Claim 16, wherein the gelling or suspension agent is selected from the group consisting of xanthan gum, acacia, tragacanth, and a mixture thereof.
- 31. (Currently Amended) The topical composition according to Claim 9, in which said at least one discontinuous phase consists of is the eutectic mixture.
- 32. (Currently Amended) The topical composition according to Claim 14, in which the pharmaceutically acceptable

Serial No.: 09/423,715

Filed: January 12, 2000

Page: 9

carrier is substantially hydrophilic, said carrier essentially consisting consists of water as the continuous phase.

- 33. (Canceled)
- 34. (Previously presented) The method according to Claim 23, in which said at least one discontinuous phase consists essentially of the eutectic mixture.
- 35. (Currently Amended) The method according to Claim 34, in which said at least one discontinuous phase consists of is the eutectic mixture.
- 36. (Currently Amended) The method according to Claim 23, in which the pharmaceutically acceptable carrier is substantially hydrophilic, said carrier comprising substantially water as the continuous phase.
- 37. (Currently Amended) The method according to Claim 36, in which the pharmaceutically acceptable carrier is substantially hydrophilic, said carrier essentially consisting consists of water as the continuous phase.